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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/511,115

06/23/2005

Ola Karlsson

1103326-0781

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03/25/2009

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EXAMINER

WU, IVES J

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

03/25/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/511,115	Applicant(s) KARLSSON ET AL.	
	Examiner IVES WU	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-16 and 27-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-16 and 27-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/3/2008;1/26/2009;3/6/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

(1). Applicants' Request-for-Continued Examination (RCEX) filed on 1/26/2008; Amendments and Remarks filed on 12/2/2008; Information Disclosure Statements filed on 12/3/2008, 1/26/2009, 3/6/2009 have been received.

Claims 3-4, 6-8, 27-32 are amended. Claims 1-2, 17-26 are cancelled before.

Accordingly, the 112 2nd rejections for claims 3-16, 27-32 in prior Office Action dated 9/3/2008 is withdrawn.

The rejections of claims 7-8 are revised and are presented with rest of claims in the following.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

(2). **Claim 7** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 7, it recites: wherein the range 20 to 60% by weight; and emulsifying agent. It is unclear the cited range which does not have meaning in the instant claim. Therefore, claim 7 is rejected.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

(3). **Claims 3-8, 31** are rejected under 35 U.S.C. 103(a) as being unpatentable over Reinecke et al (US04056497) in view of Greenwald et al (US03944513).

Reinecke et al (US004056497) disclose a acrylic ester copolymers obtained by copolymerizing acrylic esters with α -haloalkanecarboxylic acid vinyl esters and α,β -ethylenically unsaturated carboxylic acids and optionally other unsaturated monomers in **aqueous dispersion**. The copolymers **can be cross-linked with alkalies after the polymerization** (Abstract, line 1-5).

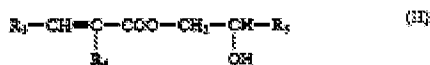
The present patentee's invention provides a process for the preparation of aqueous copolymer dispersions capable of being cross-linked in the presence of alkalies by polymerization of a mixture of:

- a. 60 to 95 wt%, calculated on the monomer mixture, of at least one acrylic acid ester and/or methacrylic acid ester of a saturated aliphatic alcohol having from 1 to 20 carbon atoms,
- b. 0 to 40 wt%, calculated on the monomer mixture, of monomers the homopolymers of which have 2nd order Tg of from -40°C to +150 °C and
- c. 0.1 to 10 wt%, calculated on the monomer mixture, of an α -haloalkanecarboxylic acid vinyl esters of the formula (I)



wherein R₁ and R₂ each represents hydrogen or an alkyl radical having from 1 to 3 carbon atoms and X is fluorine, chlorine, bromine or iodine, in aqueous dispersion in the presence of emulsifiers and/or protective colloids and of free radical initiators, which process comprises using as further reactive monomers

- d. 0.1 to 10 wt%, calculated on the monomer mixture of, α,β -ethylenically unsaturated carboxylic acids having from 3 to 8 carbon atoms or their partial ester with saturated aliphatic alcohols having from 1 to 20 carbon atoms and,
- e. 0 to 10 wt%, calculated on the monomer mixture, of monomers containing hydroxyl groups and having the formula (II)



wherein R₃ is hydrogen, a methyl group or the group -COOR₆, R₄ and R₅ each is hydrogen or a methyl group and R₆ is hydrogen or an alkyl group having from 1 to 12 carbon atoms.

(Col. 1, line 57 – Col. 2, line 32)

The dispersions of patentee's invention are prepared by free radical polymerization of the monomers in **aqueous dispersion using emulsifiers**, protective colloids and, optionally regulators (Col. 3, line 12-15). The polymerization temperature is within the range of from 0 °C to + 100 °C, preferably from 20° to 80°C (Col. 3, line 27-29). A foil of polyethylene terephthalate of a 2.5 cm X 20 cm dimension was provided with an adhesive layer 0.3 mm thick (application

in wet state). After drying, the foil was joined under slight pressure to a carefully cleaned steel sheet for measurement of the resistance to peeling (kp/2.5 cm) (Col. 6, line 28-34).

As to the components of acrylic acid or an ester in the range 40 to 80 wt% , methacrylic acid or an ester in the range 20 to 60 wt% in **claims 3-4**, Reinecke et al disclose component (a) from 60 to 95 wt% including at least one acrylic acid ester and methacrylic acid ester of a saturated aliphatic alcohol having C₁₋₂₀. The range of 60 to 95wt% would include the acrylic acid ester such as ethyl acrylate in the range from 40 to 80 wt% and methacrylic acid ester such as methyl methacrylate in the range from 20 to 60 wt% as claimed.

As to the polymerizable surfactant in the range 0.01 to 9 wt% in **claims 3-4** and **31**, Reinecke et al disclose the component (e) having the formula (II) which is equivalent to formula (I) as claimed, when the setting of patentee's formula (II) are R₃ = H atom, R₄ = H atom or methyl group, R₅ = H, and setting of applicant's formula (I) are R₂ = H atom, m = 1. Since the disclosure of the monomer by Reinecke et al is identical to the formula (I) as claimed. It is reasonable to presume that the component (e) of Reinecke et al would fulfill the utility to be a polymerizable surfactant as presently claimed in light of their chemical similarity. The burden is shifted to applicants to establish that the polymerizable surfactant of the present claims is not the same as or obvious as that set forth by Reinecke et al.

As to an aqueous film coating dispersion for pharmaceutical formulations in **independent claim 3-4**, because the composition of aqueous polymer dispersion disclosed by Reinecke et al (US04056497) is substantially identical to the aqueous film coating dispersion of applicants, it will be useful in film coating for pharmaceutical formulations as well. The intended use is not considered as limitation and of no significance in the claim construction.

As to substantially free of residual emulsifying agent which is removed after the polymerization reaction in **independent claims 3-4**, Reinecke et al is silence about removal of emulsifier.

However, Greenwald et al (US03944513) **teach** purification of polymer dispersions with adsorbent carbon particles (Title).

The advantage of removing emulsifiers is for the reasons that aqueous dispersions of vinyl polymers often contain impurities, including volatile and nonvolatile materials, which may impart undesirable properties to the polymer such as haze, color and odor, and detract from

desirable properties such as strength, toughness, flexibility, water resistance and electrical properties. Such impurities may include un-polymerized monomers, initiators such as potassium persulfate, chain transfer agent such as mercaptans, emulsifiers, impurities introduced with these materials, and the reaction products or degradation products thereof. The impurities may be in or on the polymer particles as well as in the aqueous phase (Col. 1, line 9-21).

Therefore, it would have been obvious at time of the invention to remove the emulsifier disclosed by Greenwald et al for the aqueous acrylate ester copolymer of Reinecke et al in order to obtain the above-cited advantage.

As to the aqueous film coating dispersion for pharmaceutical formulations, monomers, their wt percentage, formula (I) of the monomer and emulsifier being removed after the polymerization in **claims 5-6**, the disclosure of Reinecke et al (US004056497) is incorporated herein by reference, the most subject matters as currently claimed have been recited in applicants' claims 3 and 4, and have been discussed therein.

As to the molecular weight of emulsifier to be less than 15kD in **claims 5 and 6**, in view of substantially identical aqueous polymer dispersion disclosed by Reinecke et al, and by applicants, it is examiner's position to believe that the emulsifier of prior art would inherently possess the molecular weight as claimed. Since USOPTO does not have facilities to perform the measurement, the burden now is shifted to applicants to prove otherwise. In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

As to emulsifying agent to be the polymerizable surfactant which acts as an emulsifier during the polymerization reaction in **claim 7**, in view of the substantially identical polymerizable surfactant disclosed by Applicants, and by Reinecke et al, it would be an emulsifier during the polymerization of Reinecke et al as well.

As to emulsifying agent to be the monomer of formula I which acts as a emulsifier during the polymerization reaction in **claim 8**, in view of the substantially identical monomer formula I disclosed by Applicants, and by Reinecke et al, it would be an emulsifier during the polymerization of Reinecke et al as well.

(4). **Claims 9-14** are rejected under 35 U.S.C. 103(a) as being unpatentable over combined teaching of Reinecke et al (US004056497), Greenwald et al (US03944513) and Barry et al (US005055306) for the same rationale recited in prior Office Action dated 9/3/2008.

(5). **Claims 15 and 16** is rejected under 35 U.S.C. 103(a) as being unpatentable over combined teaching of Reinecke et al (US004056497), Greenwald et al (US03944513), Barry et al (US005055306), further in view of Chen (US005939578A), evidenced by Jonsson et al (US004957745) for the same rationale recited in prior Office Action dated 10/31/2007.

(6). **Claims 27-30 and 32** are rejected under 35 U.S.C. 103(a) as being unpatentable over Reinecke et al (US04056497) in view of Greenwald et al (US03944513), further in view of Contrada et al (US06646046B2) and Zellstoffwerke (GB01141165) for the same rationale recited in prior Office Action dated 10/31/2007.

Response to Arguments

(7). Applicant's arguments filed on 12/2/2008 have been fully considered but they are not persuasive.

In regards to the arguments that prior art Reinecke et al (US 4056497) disclose the aqueous copolymer dispersion including reactive monomers c) and d) that are not disclosed in Applicants' aqueous film coating dispersion. Furthermore, Applicants submit that inclusion of reactive components c) and d) of Reinecke would offset the chemical interaction among the monomers of claimed invention with a reasonable expectation that antisticking properties of the resulting copolymer/dispersion would be different from those are observed with the claimed invention (page 9, current Remarks).

Examiner respectfully disagrees because Applicants' instant claim cites: **comprises**, which is **open language** to allow other components to be in the coating dispersion.

Concerning the teaching of prior art Greenwald et al (US 3944513), the teaching cited at Col. 1, line 9-21 is a general teaching for definition of impurities in aqueous dispersion of vinyl polymers. The teaching cited at Col. 3, line 33-39 describes an **option** for the removal of impurities since it depends on the requirements of the product, such as the teaching cited at col.

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6, line 49-51, the dispersion **may** contain nonionic or ionic surface active agents, or both, although in some cases, **no dispersant need to be present**. Conclusively, Greenwald et al (US 3944513) teach the removal of impurities from aqueous dispersion.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IVES WU whose telephone number is (571)272-4245. The examiner can normally be reached on 8:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Duane Smith can be reached on 571-272-1166. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Examiner: Ives Wu

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Date: March 21, 2009

/Frank M. Lawrence/

Primary Examiner, Art Unit 1797